REMARKS

The remarks herein are responsive to the Final Office Action dated April 15, 2008. Upon entry of the foregoing amendments, Claims 1-2 and 4-44 remain pending. Claims 1, 8, 23, 24, 33, 36, and 37 have been amended. New Claims 41-44 have been added, which are supported by at least the non-limiting embodiments described in paragraph [0022] of the originally-filed specification.

Rejection of the Claims 35 U.S.C. § 112

Claims 23, 24, and 36 stand rejected under 35 U.S.C. § 112, as failing to particularly point out and distinctly claim the subject matter of the invention. Applicant has amended Claims 23, 24, and 36, as shown above, to provide proper antecedent basis and respectfully submits that Applicant has adequately addressed these rejections. Accordingly, Applicant respectfully requests withdrawal of the § 112 rejections of Claims 23, 24, and 36.

Rejection of the Claims Under 35 U.S.C. § 102

Claims 8, 10-12, 15-20, 24, 25, 29, 30, and 32 stand rejected under 35 U.S.C. § 102 as being anticipated by Pilliar (U.S. Patent No. 3,855,638). Applicant has amended Claim 8 as shown above.

The prosthesis in Pilliar includes a coating with "pore and pore size distributions substantially uniform from the coating substrate interface to the surface of the coating." *See* Pilliar, col. 3 at lines 27-30. Pilliar states that "it is **essential** that the interstitial pore size **exceed about 50 microns**" in order for the coating to be able to sustain bone, or other hard tissue growth. *See* Pilliar, col. 3 at lines 52-54; *see also* Pilliar, col. 3 at lines 61-63; col. 6 at lines 23-25, 43-48 (emphasis added).

Claim 8, as amended above, recites *inter alia*: "applying at least one layer of a biocompatible metal or an alloy thereof to a virgin surface of the implant to produce an implant surface comprising an open-pored structure with a porosity in a range of between about 20% and 85%; and producing a surface micro-structure on the open-pored structure." Applicant submits that Pilliar fails to disclose, teach, or suggest all of the limitations of amended Claim 8. For example, as discussed during the Examiner interview, Pilliar does not disclose or teach, among

other things, two levels of surface structure. The prosthesis of Pilliar has only one level of structure, that being the open-pored structure produced by sintering a metallic powder to the implant surface.

As discussed above, Pilliar has only one level of surface structure (i.e., the contact surface roughness of 50 μm). Thus, Applicant submits that amended Claim 8 is allowable over Pilliar. Claims 10-12, 15-20, 24, 25, 29, 30, and 32 depend from amended Claim 8 and are therefore likewise allowable over Pilliar, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Rejection of the Claims Under 35 U.S.C. § 103

Claims 8, 11-14, 22, 23 and 31

Claims 8, 11-14, 22, 23, and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shimamune (U.S. Patent No. 5,034,186). Applicant has amended Claim 8.

Shimamune discloses a process for providing a titanium composite having a porous surface. The process of Shimamune prepares a mixture of titanium and magnesium powders and a binder. Shimamune sinters this mixture onto the implant surface and removes the magnesium to create a porous surface. See Shimamune, col. 1 at l. 59 – col. 2 at l. 2. "Typically, a magnesium powder having a particle size of from 100 to 2,000 μm is used in a volume ratio of from 5 to 75% of the powder mixture." Shimamune, col. 2 at ll. 63-66.

Applicant submits that Shimamune fails to disclose, teach, or suggest all of the limitations of amended Claim 8. For example, like Pilliar, Shimamune does not disclose or teach, among other things, an open-pored surface layer having a surface micro-structure on the open-pored structure. Rather, Shimamune **only** teaches producing a porous surface layer in a titanium or titanium alloy composite. Thus, Applicant submits that amended Claim 8 is allowable over Shimamune. Claims 11-14, 22, 23, and 31 depend from amended Claim 8 and are therefore likewise allowable over Shimamune, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Claims 1, 2, 4-7, 26-28, 33-36

Claims 1, 2, 6, 7, and 26-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pilliar in view of Steinemann (U.S. Patent No. 5,456,723). Applicant has amended Claim 1.

Steinemann discloses a metallic implant having a contact surface including pits. The pits are created with a reducing acid to have a magnitude of 2 μm or less. *See* Steinemann, col. 3 at lines 7-12, 23-25, 46-54. Motivating the 2 μm maximum pit size (i.e., maximum contact surface roughness of 2μm or less), Steinemman reports that "[a]ctual tests performed on implants according to the invention showed that a porous contact surface on a metallic implant is able to meet the conditions required for making the mating bone intergrow with the implant along the contact surface and speedily form a strong and durable bond **provided that the contact surface displays a micro-roughness** with pits of the order of magnitude **of 2 μm or less**." Steinemann, col. 3 at ll. 17-25 (emphasis added). The pits can be superimposed upon a larger micro-roughness created by sandblasting. *See* Steinemann, col. 3 at ll. 7-12, 46-54.

The Examiner asserts that Steinemann discloses a micro-roughness applied to a porous surface. Applicant disagrees and submits that Steinemann instead discloses a micro-roughness applied only to pits or a virgin surface. Notably, Steinemann indicates that the "porous surface" is defined by the micro-structure, and not that this micro-structure is applied to a pre-existing porous surface. For example, in Steinemann, "roughness" is defined as a quantifiable property of a "porous surface," and thus the "micro-roughness" is the "porous surface." *See* Steinemann, col. 2 at ll. 14-31 (defining "roughness"), col. 1 at ll. 58-63 (loosely equating "surface roughness," "porous designs," and "sandblasting").

Steinemann states that "microroughness . . . may be applied directly onto the contact surface, or else be superimposed upon micro-roughness... produced for example by sandblasting." Steinemann, col. 3 at l. 67 - col. 4 at l. 5. However, as discussed in the previous Amendment and in the Examiner Interview, the pits created by sandblasting in Steinemann are not "open-pores" as recited, among other features, in amended Claim 1. Paragraph [0008] of Applicant's originally filed specification explains why the pits of Steinemann do not produce the cavities or open-pores that allow sufficient growth of the bone into the surface of the implant.

For further understanding of the open-pores and cavities as defined in the application, Applicant points the Examiner to paragraphs [0032] and [0050].

In regard to the combination of an open-pored surface layer and a shallow roughening as recited in e.g. Claim 1, Applicant submits that it would not be obvious to one of ordinary skill in the art to combine Pilliar and Steinemann to provide the open-pored biocompatible surface layer of amended Claim 1. Notably, Pilliar and Steinemann teach away from each other, and therefore teach away from a combination with each other. For example, Pilliar stresses that it is **essential** that the pore size be **greater than 50 μm** to produce the surface roughness needed for hard tissue ingrowth (i.e., that it is essential for the surface roughness to be greater than 50 μm). Pilliar, col. 3 at ll. 51-63. Contrary to Pilliar, Steinemann finds acceptable results **only** with the contact surface of the implant having a surface roughness **less than** 20 μm and explicitly contrasts its invention with prior art, such as Pilliar, that teach that contact surface roughnesses of **more than** 20 μm are **required to achieve an optimum bond** between bone and implant. *See* Steinemann, Table 1, col. 6 at ll. 29-33. Instead of combining larger open-pores (such as those in Pilliar) with the micro-structure, as Examiner suggests is obvious, Steinemann claims a surface with roughness spacing less than 10 μm.[1]

Thus, Steinemann does not show a micro-structure superimposed on a porous surface, but instead a micro-structure defining a porous surface. Further, Steinemann emphasizes that its "completely new, unexpected and surprising . . . results" indicate that a smaller structure should be used **instead** of a larger macro-structure, and **not** that this smaller structure should be added to a larger macro-structure. Steinemann, col. 6 at ll. 21-33. As described by Steinemann, this finding "stands in perfect contrast to opinions expressed so far in literature," such as e.g. Pilliar. As noted by the Supreme Court's decision in *KSR Int'l. v. Teleflex, Inc.*, a finding of nonobviousness is more likely when the prior art references teach away from a combination of elements. *See KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007).

Further, as the M.P.E.P. instructs, "[i]f the proposed modification or combination of the prior art would **change the principle of operation of the prior art invention being modified**,

[1] Applicant notes that comparison of Steinemann at Table 1 and col. 6 at lines 29-33 show that "surface roughness" is equivalent to roughness spacing. Thus, the maximum peak-to-valley height is less relevant.

then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. § 2143.01 VI (emphasis added). As discussed above, Pilliar and Steinemann present each other as **conflicting options**, and the principle of each teaches away from combination with the other. That is, the modification of the contact surface taught in Pilliar with the teachings of Steinemann would be **contrary to the expressly stated principle** in Pilliar that "[i]n order for the porous adherent coating to be able to sustain bone, or other hard tissue growth, it is **essential** that the interstitial pore size [(i.e., the contact surface roughness)] **exceed about 50 microns.**"

Therefore, modifying the contact surface of Pilliar with the teachings of Steinemann would change the principle of operation expressly stated in Pilliar. As cited above, language in Steinemann is symmetrically hostile towards combination with prior art such as Pilliar. It therefore cannot be said that such combinations would (i) yield predictable results, (ii) be obvious to try, or (iii) be suggested, taught, or motivated in the prior art. Accordingly, Applicant submits that one of ordinary skill in the art would not combine Steinemann with Pilliar, and that the Examiner has therefore not established a prima facie case of obviousness.

In view of the above, Applicant submits that amended Claim 1 is allowable over Pilliar in view of Steinemann. Pilliar and Steinemann teach away from combination with each other, so that one of ordinary skill in the art would have no reasonable expectation of success in combining Pilliar with Steinemann to provide the open-pored biocompatible surface layer of amended Claim 1. As discussed above, Applicant also submits that the Office Action has not established a prima facie case of obviousness based on Pilliar in combination with Steinemann.

Claims 2, 4-7, and 26-28 depend from amended Claim 1 and are therefore likewise allowable over the prior art cited, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Further, Applicant notes that independent Claim 1 has been amended to recite, *inter alia*, a layer with a particle size "in a range of approximately 50 μm to 800 μm." Applicant respectfully submits that this amendment better clarifies the claimed subject matter.

Claims 1, 4, and 5

Claims 1, 4, and 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shimamune in view of Steinemann. Independent Claim 1 has been amended.

The Examiner asserts that, because Shimamune discloses a volume ratio 5-75% magnesium powder, the sintered product will have a porosity of approximately 5-75%. Under the same reasoning, the pores of Shimamune would have the same pore size as the particle size of the magnesium powder, that being 100 to 2,000 μm, so that the **surface roughness of Shimamune would be on the order of 100 μm to 2,000 μm.** *See* Shimamune, col. 2 at ll. 64-66.

As discussed above, Steinemann teaches away from a contact surface roughness greater than 20 μm. Accordingly, modifying the surface taught in Shimamune with the teachings of Steinemann would change the principle of operation expressly stated in Shimamune. Therefore, in view of MPEP § 2143.01 VI it cannot be said that one of ordinary skill in the art would combine Steinemann with Shimamune. Applicant therefore submits that the Examiner has not established a prima facie case of obviousness based on Shimamune and Steinemann.

In view of the above, Applicant submits that amended Claim 1 is allowable over Shimamune in view of Steinemann. Steinemann teaches away from the combination with Shimamune, so that one of ordinary skill in the art would have no reasonable expectation of success in combining Shimamune with Steinemann to provide the open-pored biocompatible surface layer of amended Claim 1. As discussed above, Applicant also submits that the Office Action has not established a prima facie case of obviousness based on Shimamune in combination with Steinemann.

Claims 4 and 5 depend from amended Claim 1 and are therefore likewise allowable over the prior art cited, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Claims 33-36

Claims 33-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rowe (U.S. Pat. No. 4,542,539) in view of Steinemann. Independent Claim 33 has been amended.

Rowe discloses a graded porous coating, with particle size generally increasing from the metallic body toward the surface of the coating. *See* Rowe, Abstract. Notably, the surface of Rowe utilizes **pore sizes ranging from 100 to 500 μm** at the bone interface "such as to

encourage bone ingrowth," which provide a very rough contact surface of **100 μm to 500 μm**. See Rowe, col. 5 at ll. 38-40. Further, Rowe discloses that "[i]n the outer 0.005'' of the outer layer of coating, the particles may be distributed so that . . . some pores may be as large as **600 micrometers** in size." Rowe, col. 5 at ll. 40-44 (emphasis added).

As discussed above, Steinemann teaches away from the contact surface roughness of Rowe by emphasizing that acceptable results for intergrowth with bone are achieved **only** with a contact surface roughness of less than 20 μm. Further, Steinemann explicitly contrasts its invention with prior art that teach that contact surface roughnesses of **more than** 20 μm are **required to achieve an optimum bond** between bone and the implant. *See* Steinemann, Table 1, col. 6 at lines 29-33. Accordingly, Applicant submits that modifying the surface of Rowe with the teachings of Steinemann would change the principle of operation of Rowe, so that Rowe and Steinemann cannot be combined to establish prima facie case of obviousness per M.P.E.P. § 2143.01 VI.

In view of the above, Applicant submits that amended Claim 33 is allowable over Rowe in view of Steinemann. Rowe and Steinemann teach away from the combination with each other, so that one of ordinary skill in the art would have no reasonable expectation of success in combining Rowe with Steinemann to provide the method of amended Claim 33. As discussed above, Applicant also submits that the Office Action has not established a prima facie case of obviousness based on Rowe in combination with Steinemann.

Claims 34-36 depend from amended Claim 33 and are therefore likewise allowable over the prior art cited, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Further, Applicant notes that independent Claim 33 has been amended to recite, *inter alia*, a layer with a particle size "in a range of approximately 50 μm to 800 μm." Applicant respectfully submits that this amendment better clarifies the claimed subject matter.

Claims 37-40

Claims 37-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee. Independent Claim 37 has been amended.

Like Steinemann, Lee discloses a microstructure that can be superimposed over pits, so that the porosity disclosed in Lee is not an open-pored structure but pits created via sand blasting. *See* Lee, col. 7 at l. 66 through col. 8 at l. 12. However, independent Claim 37 recites *inter alia*: "a surface micro-structure applied to the open-pored implant surface, the micro-structure comprising pits." (emphasis added) As discussed above and in the previous Amendment, pits such as those in Lee do not allow the same bone ingrowth as an open-pored implant surface as that claimed. Thus, Applicant respectfully submits that Claim 37 is allowable over Lee. Claims 38-40 depend from Claim 37 and are therefore likewise allowable over Lee, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Applicant further notes that Claim 37 has been amended to recite, *inter alia*, "a particle size in the range from approximately 50 μm to 800 μm." Applicant respectfully submits that this amendment better clarifies the claimed subject matter.

New Claims

Applicant has added new claims 41-44, which depend from Claims 1, 8, 33 and 37, respectively. Applicant submits that claims 41-44 are likewise allowable over the cited art, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features no taught or suggested by the cited art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/722,697	A METHOD OF SURFACE FINISHING A BONE IMPLANT	12/22/2005
12/092,545	OPEN-PORE BIOCOMPATIBLE SURFACE LAYER FOR AN IMPLANT, METHODS OF PRODUCTION AND USE	5/2/2008

CONCLUSION

For at least the forgoing reasons, the Applicant believes that Claims 1-2 and 4-44 are allowable over the art of record and are in condition for immediate allowance.

The Applicant respectfully submits that any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the limitation discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. The Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence, disclaimer or estoppel is intended or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. The Applicant may not have presented in all cases, all arguments concerning whether the applied references can be properly combined or modified in view of the deficiencies noted above, and Applicant reserves the right to later contest whether the cited references can be properly combined or modified.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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AMEND

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